

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Carcagno *et al.*

Appl. No. 09/830,968

Filed: May 3, 2001

For: **Methods for the Massive Culture of
Cells Producing Recombinant
Human Erythropoietin**

#6

Art Unit: *To Be Assigned*

Examiner: *To Be Assigned*

Atty. Docket: 1909.0040002/JAG/CMB

Information Disclosure Statement

Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language documents AT3, AR4, AS4 and AT4 cited on Form PTO 1449:

Documents AT3, AR4, AS4 and AT4 are in the French language. No English translations are readily available. These documents appear to show evidence of a substance isolated from blood capable of regulating hematopoiesis.

Document AT11 is in a foreign language. An English language abstract is on the first page of this document.

The Examiner's attention is directed to the following co-pending U.S. Patent Applications, which are directed to related technical subject matter:

U.S. Patent Application No. 09/830,967, filed May 3, 2001, submitted herewith as Document AS17; and

U.S. Patent Application No. 09/830,964, filed May 3, 2001, submitted herewith as Document AT17.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

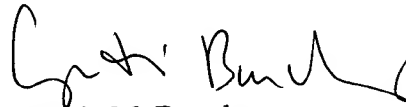
This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Cynthia M. Bouchez

Agent for Applicants

Registration No. 47,438

Date: November 6, 2001

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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 1909.0040002/JAG/CMB	APPLICATION NO. 09/830,968
	APPLICANT Carcagno <i>et al.</i>	
	FILING DATE May 3, 2001	GROUP To Be Assigned

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	4,667,016	05/19/1987	Lai <i>et al.</i>	530	397	06/20/1985
	AB1	4,667,195	06/30/1987	Hewick <i>et al.</i>	530	397	01/11/1985
	AC1	4,703,008	10/27/1987	Lin	435	240.2	11/30/1984
	AD1	4,806,524	02/21/1989	Kawaguchi <i>et al.</i>	514	8	10/03/1985
	AE1	5,010,002	04/23/1991	Levinson <i>et al.</i>	435	69.2	03/22/1990
	AF1	5,547,933	08/20/1996	Lin	514	8	06/07/1995
	AG1	5,618,698	04/08/1997	Lin	435	69.4	06/06/1995
	AH1	5,688,679	11/18/1997	Powell	435	240.2	10/06/1993
	AI1	5,756,349	05/26/1998	Lin	435	325	06/06/1995
	AJ1	5,783,559	07/21/1998	Florin-Robertsson <i>et al.</i>	514	12	01/10/1994
	AK1						

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 86/03520 ✓	06/19/1986	WIPO/PCT			Yes No
	AM1	WO 98/00530 ✓	01/08/1998	WIPO/PCT			Yes No
	AN1	WO 00/27419 ✓	05/18/2000	WIPO/PCT			Yes No
	AO1	WO 00/27869 ✓	05/18/2000	WIPO/PCT			Yes No
	AP1	WO 00/27997	05/18/2000	WIPO/PCT			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	1	Andersen, D.C. and Goochee, C.F., "The effect of cell-culture conditions on the oligosaccharide structures of secreted glycoprotein," <i>Curr. Op. Biotech.</i> 5:546-549, Current Biology Ltd. (1994).
	AS	1	Bondurant, M.C. and Koury, M.J., "Anemia Induces Accumulation of Erythropoietin mRNA in the Kidney and Liver," <i>Mol. Cell. Biol.</i> 6:2731-3, American Society for Microbiology (1986).
	AT	1	Borsook, H., <i>et al.</i> , "Polycythemic Response in Normal Adult Rats to a Nonprotein Plasma Extract from Anemic Rabbits," <i>Blood</i> 9:734-742, Grune and Stratton, Inc. (1954).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 00/28066 ✓	05/18/2000	WIPO/PCT			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	2	Bowie, J.U., <i>et al.</i> , "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions," <i>Science</i> 247:1306-1310, American Association for the Advancement of Science (1990).
AS	2	Brown, P.R. and Krstulovic, A.M., "Practical Aspects of Reverse-Phase Liquid Chromatography Applied to Biochemical and Biomedical Research," <i>Anal. Biochem.</i> 99:1-21, Academic Press, Inc. (1979).
AT	2	Burg, J., <i>et al.</i> , "Human erythropoietin recombinant production by fermentation and protein purification using a series of chromatographic steps," <i>Chem. Abstracts</i> 126:315 Abstract No. 57095j, American Chemical Society (1997).

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>3</u>	Busuttil, R.W., <i>et al.</i> , "The Cytological Localization of Erythropietin in the Human Kidney Using the Fluorescent Antibody Technique," <i>Proc. Soc. Exp. Biol. Med.</i> 137:327-330, Academic Press, Inc. (1971).
	AS	<u>3</u>	Busuttil, R.W., <i>et al.</i> , "Localization of Erythropoietin in the Glomerulus of the Hypoxic Dog Kidney Using a Fluorescent Antibody Technique," <i>Acta Haemat.</i> 47:238-242, S. Karger (1972).
	AT	<u>3</u>	Carnot, M.P. and Deflandre, C., "Sur l'activité hémopoiétique 'du sérum au cours de la régénération du sang," <i>C.R. Acad. Sci.</i> 143:384-386, (1906).

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>4</u>	Carnot, M.P. and Deflandre, C., "Sur l'activité hémopoïétique des différents organes au cours de la régénération du sang," <i>C.R. Acad. Sci.</i> 143:432-435 (1906).
	AS	<u>4</u>	Carnot, M.P., "Sur le Mécanisme de L'hyperglobulie Provoquée par le Sérum D'animaux en Rénovation Sanguine," <i>C.R.H. Sean. Mem. Soc. Biol.</i> 111:344-346, Libraires de L'Académie de Médecine (1906).
	AT	<u>4</u>	Carnot, M.P., "Sur L'activité Cytopoïétique du Sang et des Organes Régénérés au Cours des Régénérations Viscérales," <i>C.R.H. Sean. Mem. Soc. Biol.</i> 111:463-465, Libraires de L'Académie de Médecine (1906).

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>5</u>	Caro, J. and Erslev, A.J., "Biologic and immunologic erythropoietin in extracts from hypoxic whole rat kidneys and in their glomerular and tubular fractions," <i>J. Lab. Clin. Med</i> 103:922-931, C.V. Mosby Company (1984).
	AS	<u>5</u>	Caro, J., <i>et al.</i> , "Erythropoietin Production by an Established Kidney Proximal Tubule Cell Line (LLCPK ₁)," <i>Exp. Hematol</i> 12:357, Springer-Verlag (1984).
	AT	<u>5</u>	Caro, J., <i>et al.</i> , "Erythropoietin in liver tissue extracts and in liver perfusates from hypoxic rats," <i>Am. J. Physiol.</i> 244:E431-E434, American Physiological Society (1983).

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	AN						Yes No
	AO						Yes No
	AP						Yes No
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	<u>6</u>	Dinkelaar, R.B., <i>et al.</i> , "Metabolic Studies on Erythropoietin (Ep): II. The Role of Liver and Kidney in the Metabolism of Ep," <i>Exp. Hematol.</i> 9:796-803, Allen Press, Inc. (1981).				
	AS	<u>6</u>	Dornfest, B.S., <i>et al.</i> , "Hepatic production of erythropoietin in a phenylhydrazine-induced compensated hemolytic state in the rat," <i>J. Lab. Clin. Med.</i> 102:274-85, C.V. Mosby Company (1983).				
	AT	<u>6</u>	Dornfest, B.S., <i>et al.</i> , "Recovery of an Erythropoietic Inducing Factor from the Regenerating Rat Liver," <i>Ann. Clin. Lab. Sci.</i> 11:37-46, Institute for Clinical Science (1981).				
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	Z	Erslev, A., "Humoral Regulation of Red Cell Production," <i>Blood</i> 8:349-357, Grune and Stratton, Inc. (1953).
AS	Z	Erslev, A.J., " In Vitro Production of Erythropoietin by Kidneys Perfused With a Serum-free Solution," <i>Blood</i> 44:77-85, Grune and Stratton, Inc. (1974).
AT	Z	Erslev, A.J. and Caro, J., "Physiologic and Molecular Biology of Erythropoietin," <i>Med. Oncol. Tumor Pharmacother.</i> 3:159-164, Pergamon Press (1986).

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>8</u>	Eschbach, J.W., <i>et al.</i> , "Correction of the Anemia of End-Stage Renal Disease with Recombinant Human Erythropoietin," <i>New Eng. J. Med.</i> 316:73-78, Massachusetts Medical Society (1987).
	AS	<u>8</u>	Fisher, J.W. and Birdwell, B.J., "The Production of an Erythropoietic Factor by the In Situ Perfused Kidney," <i>Acta. Haemat.</i> 26:224-232, S. Karger (1961).
	AT	<u>8</u>	Fisher, J.W., <i>et al.</i> , "Localization of Erythropoietin in Glomeruli of Sheep Kidney by Fluorescent Antibody Technique," <i>Nature</i> 205:611-612, Macmillan Magazines Ltd. (1965).

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	AL						Yes No
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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	2	Fisher, J.W., "Pharmacologic Modulation of Erythropoietin Production," <i>Ann. Rev. Pharmacol. Toxicol.</i> 28:101-122, Annual Reviews, Inc. (1988).
AS	2	Frenkel, E.P., <i>et al.</i> , "Some Observations on the Localization of Erythropoietin," <i>Ann. N.Y. Acad. Sci.</i> 149:292-293, New York Academy of Sciences (1968).
AT	2	Gordon, A.S., <i>et al.</i> , "A Plasma Extract with Erythropoietic Activity," <i>Proc. Soc. Exp. Biol. Med.</i> 86:255-258, Society for Experimental Biology and Medicine (1954).

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	AR	<u>10</u>	Han, F., <i>et al.</i> , "Cloning of a human erythropoietin cDNA and its expression in COS-7 cells," <i>Chem. Abstracts</i> Abstract No. 511352 (1996).
	AS	<u>10</u>	Hodgson, G. and Tohá, J., "The Erythropoietic Effect of Urine and Plasma of Repeatedly Bled Rabbits," <i>Blood</i> 9:299-309, Grune and Stratton, Inc. (1954).
	AT	<u>10</u>	Jacobs, K., <i>et al.</i> , "Isolation and characterization of genomic and cDNA clones of human erythropoietin," <i>Nature</i> 313:806-810, Macmillan Magazines Ltd. (1985).

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	AR	<u>11</u>	Jacobson, L.O., <i>et al.</i> , "Role of the Kidney in Erythropoiesis," <i>Nature</i> 179:633-634, Macmillan Magazines Ltd. (1957).
	AS	<u>11</u>	Jelkmann, W., <i>et al.</i> , "Extraction of Erythropoietin from Isolated Renal Glomeruli of Hypoxic Rats," <i>Exp. Hematol.</i> 11:581-588, Allen Press, Inc. (1983).
	AT	<u>11</u>	Jixian, D., <i>et al.</i> , "Study on a serum-free medium used for production of rHuEPO," <i>Bull. Acad. Mil. Med. Sci.</i> 21:244-246, Academy of Military Medical Sciences (1997).

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>12</u>	Kazal, L.A. and Erslev, A.J., "Erythropoietin Production in Renal Tumors," <i>Ann. Clin. Lab. Sci.</i> 5:98-109, Institute for Clinical Science (1975).
	AS	<u>12</u>	Krane, N.K., "The Role of Erythropoietin in the Anemia of Chronic Renal Failure," <i>H. Ford Hosp. Med. J.</i> 31:177-181, Henry Ford Hospital (1983).
	AT	<u>12</u>	Koury, S.T., <i>et al.</i> , "Localization of Erythropoietin Synthesizing Cells in Murine Kidneys by In Situ Hybridization," <i>Blood</i> 71:524-527, Grune and Stratton, Inc. (1988).

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT				ATTY. DOCKET NO. 1909.0040002/JAG/CMB		APPLICATION NO. 09/830,968	
				APPLICANT Carcagno <i>et al.</i>			
				FILING DATE May 3, 2001		GROUP To Be Assigned	

U.S. PATENT DOCUMENTS							
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>13</u>	Koury, S.T., <i>et al.</i> , "Quantitation of Erythropoietin-Producing Cells in Kidneys of Mice by In Situ Hybridization: Correlation With Hematocrit, Renal Erythropoietin mRNA, and Serum Erythropoietin Concentration," <i>Blood</i> 74:645-651, Grune and Stratton, Inc. (1989).
	AS	<u>13</u>	Kuratowska, Z., <i>et al.</i> , "Studies on the Production of Erythropoietin by Isolated Perfused Organs," <i>Blood</i> 18:527-534, Grune and Stratton, Inc. (1961).
	AT	<u>13</u>	Kurtz, A., <i>et al.</i> , "Renal mesangial cell cultures as a model for study of erythropoietin production," <i>Proc. Natl. Acad. Sci. USA</i> 80:4008-4011, National Academy of Sciences (1983).

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AR	<u>14</u>	Lacombe, C., <i>et al.</i> , "Peritubular Cells Are the Site of Erythropoietin Synthesis in the Murine Hypoxic Kidney," <i>J. Clin. Invest.</i> 81:620-623, Rockefeller University Press (1988).
AS	<u>14</u>	Liu, P., <i>et al.</i> , "Hepatic Erythropoietin (Ep) Production Following Double Partial Hepatectomy in the Rat," <i>J. Surg. Oncol.</i> 15:121-132, Alan R. Liss, Inc. (1980).
AT	<u>14</u>	Naughton, B.A., <i>et al.</i> , "Reticuloendothelial System (RES) Hyperfunction and Erythropoietin (Ep) Production in the Regenerating Liver," <i>J. Surg. Oncol.</i> 12:227-242, Alan R. Liss, Inc. (1979).

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	AR	15	Naughton, B.A., <i>et al.</i> , "Evidence for a Hepatic-Renal Antagonism in the Production of Hepatic Erythropoietin," <i>Ann. Clin. Lab. Sci.</i> 13:432-438, Institute for Clinical Science (1983).				
	AS	15	Parsons, T.F., <i>et al.</i> , "Rapid and Easy Separation of the Subunits of Bovine and Human Glycoprotein Hormones by Use of High Performance Liquid Chromatography," <i>Endocrinology</i> 114: 2223-2227, J.B. Lippincott Co. (1984).				
	AT	15	Reisman, K.R., "Studies on the Mechanism of Erythropoietic Stimulation in Parabolic Rats During Hypoxia," <i>Blood</i> 5:372-380, Grune and Stratton, Inc. (1950).				
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	AR	<u>16</u>	Schuster, J.H., <i>et al.</i> , "Physiologic Regulation and Tissue Localization of Renal Erythropoietin Messenger RNA," <i>Blood</i> 70:316-318, Grune and Stratton, Inc.(1987).				
	AS	<u>16</u>	Sherwood, J.B., <i>et al.</i> , "Erythropoietin Production by Human Renal Carcinoma Cells in Culture," <i>Endocrinology</i> 99:504-510, J.B. Lippincott Co. (1976).				
	AT	<u>16</u>	Takagaki, Y., <i>et al.</i> , "Amino Acid Sequence of the Membranous Segment of Rabbit Liver Cytochrome <i>b₅</i> ," <i>J. Biol. Chem.</i> 255:1536-1541, American Society of Biological Chemists, Inc. (1980).				
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AS	<u>17</u>	Pending Non-Provisional United States Patent Application No. 09/830,967, Carcagno <i>et al.</i> , filed May 3, 2001.
AT	<u>17</u>	Pending Non-Provisional United States Patent Application No. 09/830,964, Carcagno <i>et al.</i> , filed May 3, 2001.

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AS	<u>18</u>	International Search Report of International Application No. PCT/US99/26241, March 7, 2000.
AT	<u>18</u>	International Search Report of International Application No. PCT/US99/26240, February 22, 2000.

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	AR	<u>19</u>	International Search Report of International Application No. PCT/US99/26237, February 18, 2000.
	AS	<u>19</u>	
	AT		

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